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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/589,841 | 07/05/2007 | Jun Nakayama | BURN1110-1 | 2798 |

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| EXAMINER |
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MONTANARI, DAVID A

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| ART UNIT | PAPER NUMBER |
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1632

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06/08/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/589,841 | Applicant(s) NAKAYAMA ET AL. | |
| | Examiner David Montanari | Art Unit 1632 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-88 is/are pending in the application.
- 4a) Of the above claim(s) 21-88 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/12/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicants arguments and amendments filed on 3/12/2010 have been entered.
2. Claims 1-16 are cancelled.
3. Claims 17-20 are amended.
4. The rejection of claims 18 and 19 under 35 USC 102(b) is withdrawn in view of Applicant's amendments to the claims.
5. The rejection of claims 7 and 10 under 35 USC 112, second paragraph is moot in view of Applicant's cancelling of said claims.
6. Claims 21-88 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8/11/2009.
7. Claims 17-20 are examined in the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

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art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 17 has been amended to recite that the glycoprotein is produced by contacting a carrier polypeptide with α 4GnT (cell-free) and then further contacted again with milk containing α 4GnT. However a review of the specification provides no teaching for a method of producing a glycoprotein that comprises two contacting steps. The previous claim listing (8/17/2006) only recited one contacting step, but that this step could be done in milk (claims 13, 16 and 17).

If Applicant believes this rejection is in error they are invited to cite line and page number where a method of producing a glycoprotein is taught comprising two contacting steps with α 4GnT and milk containing α 4GnT.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The method of claim 17 is unclear as it appears that there are now two contacting steps: a cell-free contacting step and a milk contacting step. The instant specification does not support two contacting steps and it now appears that two contacting steps are required. The glycoprotein is already produced in the first contacting with α 4GnT, thus it is unclear why the glycoprotein needs to be further contacted with milk containing α 4GnT as recited in the amended claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 20 remains rejected under 35 U.S.C. 102(b) as being anticipated by Nakayama et al. (1999, PNAS, Vol. 96, pgs. 8991-8996) as evidenced by Xing et al. (1989, Immunol. Cell Biol., Vol. 67, pgs. 183-195) for reasons of record in the Non-Final rejection mailed on 11/13/2009.

Applicants have amended claim 20 to depend from the method of claim 17, which was previously indicated as being free of the prior art. However, the glycoprotein of claim 20 remains rejected as being anticipated by the teachings of Nakayama et al. since said glycoprotein is a product by process.

Since the glycoprotein of claim 20 is a product by process, the process of making carries little patentable weight. In the instant case, the process of producing a glycoprotein comprising at least one α 1,4-linked N-acetylglucosamine (α 1,4-linked GlcNAc) residue does not impart any specific property or function to the claimed glycoprotein that would distinguish it from the prior art. It is only the product, which is anticipated by the prior art and not the process, by which the product was made. This is because the final product, a glycoprotein comprising at least one α 1,4-linked GlcNAc residue is not distinguished by any particular features or characteristics resulting from the process (producing a glycoprotein in milk) by which it is made. Patentability of a

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product-by-process claim is determined by the novelty and nonobviousness of the claimed product itself without consideration of the process for making the product.

Response to Arguments

Applicant's Arguments

Applicants argue in amendment filed on 3/12/2010 that they have amended claims 18-20 to depend from claim 17, which was previously indicated as being free of the prior art and thus now include all the limitations of claim 17.

Examiner's Response

While Applicant has amended claims 18-20 to depend from claim 17 (previously indicated as free of the prior art), claim 20 remains rejected as a product by process as being anticipated by the teachings of Nakayama et al. as described above.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 1-571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Peter Paras, Jr./
Supervisory Patent Examiner, Art Unit 1632